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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/641,081	08/16/2000	Carsten Rosenow	3334.1	3725

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EXAMINER
ZHOU, SHUBO

ART UNIT	PAPER NUMBER
1631	6

DATE MAILED: 01/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/641,081	ROSENOW ET AL.	
	Examiner	Art Unit	
	Shubo "Joe" Zhou	1631	

-- The MAILING DATE of this communication app ars on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Applicants' election of Group I (claims 1-9) in Paper No. 5, filed 12/17/01, is acknowledged. Because applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants' amendment of canceling claims 10-14 is also acknowledged and entered.

Accordingly, claims 1-9 are currently pending and under examination.

Specification

The specification is objected to because of the following:

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the **elected** claims are directed. The title is directed to both methods and computer software products for transcriptional annotation whereas the elected invention is directed to methods for identifying transcribed region of a genome.

It is noted that a PTO-948 was mailed with Paper No. 4 on 9/11/01. Applicants were notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". Pursuant to the above notification, applicants are required to submit drawing corrections within the time period set for responding to this Office action.

Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action. However, in Paper No. 5, applicants fail to provide drawings with such correction. Applicants are still required to submit drawing corrections within the time period set for responding to the **present** Office action.

Claim Rejections-35 USC § 112

The following is a quotation of the **second** paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

Claims 1-16 are rejected under 35 U.S.C. 112 , second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "identifying a potentially transcribed region of a genome" in claim 1 and all its dependent claims is vague and indefinite. Does it mean that in the end, the methods as claims only identify a region that is "potentially transcribed" but not definitely transcribed? If this is the case, at what probability that the region is indeed transcribed?

The phrase "said sub-regions" in claim 6 has no antecedent basis and the claim is thus indefinite.

Clarification of the metes and bounds of the phrases are required.

Claim Rejections-35 USC § 102

The following is a quotation of the appropriate paragraph of 35 U.S.C. 102(a) that forms the basis for the rejections under this section made in this Office action:

A pers n shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 are rejected under 35 U.S.C. § 102(a) as being anticipated by Leary et al. (WO 99/67422, 29 December 1999).

Leary et al. disclose a method for mapping the position of individual transcript from a genome comprising hybridizing a plurality of nucleic acid probes with a nucleic acid sample wherein the sample comprises transcripts from the genome and the probes are from an area of the genome (page 4, first paragraph) and such probes are immobilized to a substrate (pages 7-8, the bridging paragraph). While Learly et al. do not explicitly recite identifying the transcribed region when the hybridization signal of such region is above a threshold value as required in the instant claim, Learly et al. do disclose "analyzing the pattern in which the labeled test transcripts have hybridized to the genomic subfragments on the high density grid, whereby by comparing the position of the labeled test transcripts on the high density grid to the ordered position of the overlapping genomic subfragments on said grid, the position of individual test transcripts from within the genomic sequence are mapped" (page 4, first paragraph) and computer assisted method is also used in the analysis (page 10, first paragraph). It is inherent that when comparing the position of the labeled test transcripts on the high density grid to the ordered position of the overlapping genomic subfragments on said grid by an ordinary skill in the art, either manually or with the assistance of computer, a threshold of signal value must have been determined for a signal to be considered positive and all signals above this threshold value are positive hybridizations.

Learly et al. also disclose that the probes of the genomic fragments can be singled stranded or double stranded (page 9, lines 6-9) and can be oligonucleotides of

20 or more bases (page 9, last paragraph). Further, the probes are immobilized onto such substrates as nylon membrane or glass slide (page 5, first paragraph).

Claim Rejections-35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leary et al. (WO 99/67422, 29 December 1999) in view of Lockhart et al. (US Patent No. 6,040,138, Date of Patent: Mar 21, 2000, filing date: Sep. 15, 1995).

As set forth above, Leary et al. disclose a method for mapping the position of individual transcript from a genome comprising hybridizing a plurality of nucleic acid

probes with a nucleic acid sample wherein the sample comprises transcripts from the genome and the probes are from an area of the genome (page 4, first paragraph) and such probes are immobilized to a substrate (pages 7-8, the bridging paragraph). While Learly et al. do not explicitly recite identifying the transcribed region when the hybridization signal of such region is above a threshold value as required in the instant claim, Learly et al. do disclose "analyzing the pattern in which the labeled test transcripts have hybridized to the genomic subfragments on the high density grid, whereby by comparing the position of the labeled test transcripts on the high density grid to the ordered position of the overlapping genomic subfragments on said grid, the position of individual test transcripts from within the genomic sequence are mapped" (page 4, first paragraph) and computer assisted method is also used in the analysis (page 10, first paragraph). It is inherent that when comparing the position of the labeled test transcripts on the high density grid to the ordered position of the overlapping genomic subfragments on said grid by an ordinary skill in the art, either manually or with the assistance of computer, a threshold of signal value must have been determined for a signal to be considered positive and all signals above this threshold value are positive hybridizations. Further, since Learly et al. are comparing hybridization of different regions of the genome with overlapping fragments and subfragments, it would have been obvious that in the process of comparison of the hybridization signals for the different regions, manually or with computer assisted, there would have been subregions of the genomic wherein the hybridization signals are similar and above a threshold value, thus the subregions are said transcribed regions.

Learly et al. also disclose that the probes of the genomic fragments can be singled stranded or double stranded (page 9, lines 6-9) and can be oligonucleotides of 20 or more bases (page 9, last paragraph). Further, the probes are immobilized onto

such substrates as nylon membrane or glass slide (page 5, first paragraph). Learly et al. also disclosed that the preferred embodiments in the method include using genomic fragments of bacterial species, which are prokaryotes, most particularly a human pathogen such as Streptococcus (page 10, last paragraph). Although Learly do not explicitly recite E. coli and operon, it would have been obvious that E. coli is also a common human pathogen, and operon is part of the genomic fragments. Particularly, it is well-known that prokaryotic genes are clustered as operons and it would have been obvious that genomic fragments of operons are the transcribed regions under test.

Lockhart et al. disclose methods of gene expression monitoring by hybridization to high density oligonucleotide arrays, comprising hybridizing test transcripts to genomic probes immobilized onto substrates (column 2, Summary of the invention), the exact technology as disclosed by Learly et al. Lockhart et al. disclose using mismatch control probes (column 3, third paragraph) and using background signals for the calculation and determination of signal intensity. It is well-known to ordinary skilled in the art that background signal is the result of non-specific binding of the test transcripts and the probes on the substrate.

In summary, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine the teachings and/or motivations of Learly et al. and Lockhart et al. to make and use the claimed invention. The motivation to combine is clear because both references are in the same art of using high density array for hybridization of oligonucleotide probes and transcripts. There would have been a reasonable expectation of success because both references teach and suggest all the claimed limitations and provide detailed procedures for making and using the inventions.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to:
Shubo "Joe" Zhou, Ph.D., whose telephone number is (703) 605-1158. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst Tina Plunkett whose telephone number is 703)-305-3524, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

S. "Joe" Zhou, Ph.D.

Patent Examiner

MICHAEL BORIN, PH.D
PRIMARY EXAMINER